

Standards Review
SRC_002
Rev. #: 1
Date: August 24, 2004
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**Standard Operating Procedure
Review of Standards Submitted to the National Environmental Laboratory
Accreditation Conference (NELAC)**

**NELAC Standards Review Committee
FINAL**

Reviewed by NELAC Standards Review Committee:

Date

Reviewed by NELAC Board of Directors:

Date

Approved by NELAC:

August 24, 2004
Date

1.0 Purpose

The purpose of this standard operating procedure (SOP) is to ensure that all reviews of proposed standards submitted to the National Environmental Laboratory Accreditation Conference (NELAC) are carried out in a proper, timely, and consistent manner and in accordance with the NELAC Standard and the NELAC procedures and policies.

2.0 Applicability

This SOP applies to all standards submitted to the NELAC by Standard Development Organizations (SDOs).

3.0 Summary

Standards review is the responsibility of the Standards Review Committee (SRC). The SRC will:

- a) review all standards received by NELAC from SDOs for consistency with governmental, regulatory, and NELAC requirements;
- b) prepare an assessment of the advantages and disadvantages of each standard;
- c) prepare and publish a report with recommendations for disposition of proposed standards received by the SRC;
- d) facilitate discussions of proposed standards at the NELAC interim meeting; and
- e) present proposed standards with recommendations to the NELAC membership for a vote at the NELAC annual meeting.

4.0 Definitions

Standards Review Committee (SRC) - a body of the NELAC comprised of one official from each National Environmental Laboratory Accreditation Program (NELAP) recognized accrediting authority (AA) and ten members who are officials not from a NELAP-recognized accrediting authority (Article V, Section 2, paragraph C of the NELAC bylaws).

5.0 Procedure

5.1 Reviews for Acceptability of the Standard Development Organization

- a) Confirm that the proposed standard has been developed by an organization meeting the requirements of OMB Circular A-119 (see Appendix A) and the following:
 - 1) Openness. Determine that the organization's process of developing standards is designed to be open. The organization ensures that standards are readily available, the organization allows any interested parties to review the standards, and provides a mechanism for submitting comments on those standards for consideration by the committee that develops the standard.

- 2) **Balance of Interest.** Determine that the organization has a process that defines how various segments (e.g., private vs. public or manufacturer vs. user) are distributed on committees to ensure a representative mixture of members so that a variety of interests are included. Indicate which document or material covers this condition for the organization.
 - 3) **Lack of dominance.** The standards development process shall be not be dominated by any single interest category, individual, or organization. Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints.
 - 4) **Due Process.** Determine that the organization has a written policy that describes how a standard is adopted and the process for ensuring that a variety of opinions are considered in developing the standard; e.g., a ballot process that identifies the procedure for revising a standard and the basis for submitting and/or handling a negative vote on the standard would meet these criteria.
 - 5) **Appeals Process.** Determine that the organization has a defined consensus process that ensures general agreement, but not necessarily unanimity. It shall include a process for attempting to resolve objections by interested parties, including informing the objector of the disposition of his or her objection(s) and the reasons why, and a provision allowing committee members to change their votes after reviewing the objections.
- b) Make a record of the documents and/or materials used in the confirmation.
 - c) If the proposed standard has not been developed by an acceptable SDO, the SRC chairperson will return it to the submitting party with a written explanation for the rejection.
 - d) If the SRC confirms that the proposed standard has been developed by an acceptable SDO, it will proceed with the completeness review.

5.2 Completeness Review of Proposed Standard

Confirm that the proposed standard is complete and includes all the information necessary for a review.

5.3 Technical Review of Standard

- a) The SRC will form one or more subcommittees to review standards that the SRC has accepted for review. The subcommittee(s) will be comprised of members of the SRC and/or technical experts from outside the SRC membership as necessary to provide a comprehensive review. The subcommittee(s) will be appointed by the SRC chairperson. The subcommittee(s) will include at least two members of the SRC preferably from NELAP recognized AAs.
 - 1) The SRC chairperson will provide a written task assignment to each subcommittee.
 - 2) The subcommittee(s) will conduct a review of the proposed standard according to the task assignment and provide a written report of its findings and recommendations to the SRC. It may also present its findings at one of the SRC's subsequent meetings.
- b) Once the SRC has reviewed the subcommittee's recommendations, it shall prepare a summary of

the technical review. This summary must include the findings and recommendations of the subcommittee(s) and any additional explanation needed to enhance the proceedings during the open working session at the interim meeting. This summary shall be made available on the NELAC website at least 30 days prior to the Interim meeting along with the standard that was reviewed.

- c) The SRC will hold an open working session at the NELAC interim meeting to consider all the proposed standards that have been submitted at least 90 days preceding that meeting.
- d) No later than 30 days after the interim meeting, the SRC will notify the SDO of the SRC's recommendations.
- e) The SRC will prepare a written assessment of the proposed standard that has been discussed at the interim meeting. Make available or reference (where the standard is available to the public) all proposed standards, together with the SRC's written assessment, at least 30 days prior to the annual meeting.

6.0 Quality Control

The NELAC Board of Directors and the NELAP Director will assess the performance of the SRC review process annually.

7.0 References

NELAC Chapter One, Revision 16, June 5, 2003.